510k Summary

K122073
p1/2

Special 510(k) Notification

AUG 2 2012

510(k): ELI 280 Electrocardiograph Device Summary

Submitter: **Date: July 10, 2012**

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Mortara Instrument, Inc.
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Milwaukee, WI 53224
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Contact: Amy Yang (see above)

Trade Name: ELI 280 Electrocardiograph
Common Name: Electrocardiograph
Classification Name: Electrocardiograph
(Per 21 CFR 870.2340)

Legally marketed devices to which S.E. is claimed:

The ELI 280 is an update to the ELI Series Electrocardiographs and is substantially equivalent to ELI 250(c) Electrocardiograph (K101403) and other Mortara devices presently in distribution

Description:

The proposed Mortara Instrument ELI 280 is multi-channel, resting electrocardiograph utilizing a color LCD with touch screen for display of ECG waveforms, custom keyboard, menu options and status information. The proposed modification to the ELI 280 will simultaneously acquire data from 12 lead patient cables, up to 15 leads when available. Once the data is acquired, it can be reviewed, and/or stored, and/or printed with optional resting ECG interpretation provided for physician over-read.

The ELI 280 is able to acquire, analyze, display and print electrocardiograms acquired through the Mortara front-end amplifier. The size of the screen will allow preview of the record for technician to assess the quality of the acquired ECG.

The ELI 280 utilizes a color touch screen LCD for display of ECG waveforms, custom keyboard, menu options and status information. The touch screen overlay on the LCD display allows the user to interact with the cardiograph by touching areas on the screen for select functions, input demographic parameters and navigate through menus using the touch screen interface. The keyboard is part of the ELI 280 touch screen design and allows patient data entry as well as control of the functions and options available for the unit.

The ELI 280 incorporates a thermal writer that allows printouts using several formats available to the user, from the 6+6 channels to the Cabrera formats. The writer is also used by the unit for real time, continuous rhythm printouts. The ELI 280 offers, adult and pediatric interpretation capability to assist the physician over-read of the electrocardiogram, and review the electrocardiogram to identify the best 10 second sample based on noise.

The ELI 280 is intended to be used with the Mortara Wireless Acquisition Module (WAM) and Mortara Acquisition Module (AM12) patient cables. The ELI 280 acquires ECG waveforms from the WAM or the AM12 patient cable. The ELI 280 also offers storage capability in order to retrieve or transmit stored records. Transmission can be achieved using one of the options communication media designed in the unit: LAN, WLAN, USB port and/or Modem.

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Intended Use:

The ELI 280 is intended to be a high-performance, multi-channel, interpretive electrocardiograph. As a resting electrocardiograph, ELI 280 simultaneously acquires data from multiple channels. Once the data is acquired, it can be reviewed and/or stored, and/or printed with optional resting ECG interpretation provided for physician over-read. It will be a device primarily intended for use in hospitals, but may be used in medical clinics and offices of any size.

Indications for Use:

The proposed Mortara ELI 280 Electrocardiograph is a non-invasive prescription device.

- The device is indicated for use to acquire, analyze, display and print electrocardiograms.
- The device is indicated for use to provide interpretation of the data for consideration by a physician.
- The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.
- The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.
- The device is indicated for use on adult and pediatric populations.
- The device is not intended to be used as a vital signs physiological monitor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 2 2012

Mortara Instrument, Inc.
c/o Ms. Any Yang
Regulatory Affairs Engineer
7865 N 86th Street
Milwaukee, WI 53224

Re: K122073
Trade/Device Name: ELI 280 Electrocardiograph
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: July 11, 2012
Received: July 16, 2012

Dear Ms. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122073

Indications for Use

510(k) Number (if known):_____

Device Name: **Mortara ELI 280 Electrocardiograph**

Indications for Use:

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- The device is not intended to be used as a vital signs physiological monitor.

Prescription Use ___X___ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122073

Concurrence of CDRH, Office of Device Evaluation (ODE)